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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,887	04/06/2005	Vladimir Velebny	074047-00002 (KANIA-04)	6569

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,887	VELEBNY ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *6-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 27-37* is/are rejected.

7)☒ Claim(s) *1,6- 27, 30, 32-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of group I (claims 1-5, 27-37) in the reply filed on January 22, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant filed an Information disclosure statement on February 12, 2008 and cited an international search report (reference 1 on page 2 or IDS). This report does not have a publication date, and as such is not considered.

Claim Objections

Claims 1, 27, 30, and 32-35 are objected to because of the following informalities:

In claim 1 (line 4), the word "wound" is misspelled as "would" in two places ("would healing" and "would covering").

In claims 27, 30, and 32-35, hyaluronic acid appears to be misspelled as "hyaluranic acid". Appropriate correction is required.

Claims 6-26 are objected to for being improperly presented. Withdrawn claims should be presented in their entirety (with the phrase "withdrawn" in the position where "original" or "currently amended" is present); only canceled claims may be presented as "6-26. (Canceled)." with no additional text.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant claims a composition of hyaluronic acid, iodine, and potassium iodide, which form a composition for wound healing and preventing adhesion of a wound covering to a wound. Applicant has shown how to make the composition but has not shown any ability of the composition to lessen, much less prevent adhesion of the wound covering to the wound. To prevent such adhesion would mean to eliminate any form of adhesion in every instance it is applied, applicant has most definitely not shown how one of skill in the art would use this invention to prevent wound adhesion.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples,

(4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation is high (1) in order to prevent wound adhesion completely without any form of direction in that respect (2) or examples which show the effect of the composition on wound adhesion at all (3). The nature of the invention is prevention of wound adhesion, which means eliminating any bond between the wound and the wound covering (4), the state of the prior art is such that lessening adhesion is known (5) and the skill of those in the art is high (6), however the unpredictability of treating human wounds is high (7) and the breadth of the claims is large due to claims of prevention (8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollingsbee et al (WO 97/02845, cited on applicant's IDS) in view of Tsubouchi et al. (US 6,175,053).

Claim 1 claims a composition comprising a physiologically acceptable salt of hyaluronic acid having molecular weight of 200,000 to 2,500,000, with iodine and potassium iodide which forms a composition for would healing. Claim 2 claims that the salt form is selected from sodium salt, potassium salt, lithium salt, calcium salt, magnesium salt, zinc salt, cobalt salt, or manganese salt.

Hollingsbee et al. teach compositions of hyaluronic acid having molecular weights between 50,000 to 2,000,000 (page 3, lines 27-29) and they teach that the hyaluronic acid can be in salt form, specifically sodium salt (page 3, lines 23-25). They further teach combining antibacterial agents with the hyaluronic acid such as polyvinylpyrrolidone iodine (page 4, lines 26-32). Hollingsbee et al. does not potassium iodine, however Tsubouchi et al. teach a novel wound dressing material that contains disinfectants including iodine and potassium iodine (column 2, lines 58-62). Since both compositions are directed at wound coverings for wound healing, and potassium iodide

and iodine are both extremely well known in the art for their disinfecting ability, it would have been obvious to one of ordinary skill in the art at the time of the invention to add potassium iodide to the wound treatment of Hollingsbee et al. Thus claims 1 and 2 are unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

Claim 27 claims a composition comprising iodine, potassium iodine, and hyaluranic acid. As mentioned above, hyaluranic acid is misspelled, however assuming that hyaluronic acid was intended to be claimed, the composition is also unpatentable over Hollingsbee et al. in view of Tsubouchi et al. for the same reasons as claim 1, which was discussed above.

Claims 3-4, 28, and 34 claim specific concentrations of the ingredients in claims 1 and 27 respectively, where the hyaluronic acid is in the range of 0.05-10% by weight, the iodine is in the range of 0.075-1% by weight, and the potassium iodide is in the range of 0.075-1% by weight. Hollingsbee et al. teaches that the hyaluronic acid makes up between 0.1-90% of the composition (page 4, lines 10-12), which encompasses the range claimed in the instant claims 3 and 4. Tsubouchi et al. teaches that the disinfectants are used in concentrations between 0.5-20% by weight, with the concentration being minimum to keep the wound dressing from becoming hard and fragile (column 3, lines 9-15). Thus the ranges of potassium iodine and iodine are taught by Tsubouchi et al. and claims 3-4, 28, and 34 are unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

Claim 5 claims the composition of claim 1 is in the form of a sterile aqueous solution or gel. Hollingsbee et al. teach their composition in the form of a film, however they do teach that compositions can also be used as liquids, emulsions, or gels (page 1, lines 24-30) and since the purpose of both Hollingsbee et al. and Tsubouchi et al. is to promote wound healing it would have been obvious to one of ordinary skill in the art that

the solution or gel would be sterile. Furthermore, using the composition as a gel or solution is obvious to one of ordinary skill in the art at the time of the invention since that is the most common form of topical wound healing options, and would allow for placement both on the bandage or on the wound. Thus claim 5 is obvious over Hollingsbee et al. in view of Tsubouchi et al.

Claim 29 claims the composition of claim 27, where the iodine is added to potassium iodide to form a solution and then combined with a hyaluronate solution. In claims 35-36, applicant claims the iodine is dissolved in the potassium iodide to form an iodine solution and then combining the iodine solution with the hyaluronate solution. While the Hollingsbee et al. does not specify how the hyaluronic acid and iodine were combined, since both iodine and potassium are the disinfectants and are taught together by Tsubouchi et al. it would be obvious to one of ordinary skill in the art at the time of the invention that the iodine and iodine could be combined prior to combination with the hyaluronic acid. Additionally, the compound would still contain the same components claimed in claim 27, no matter what order the ingredients were added and thus claims 29 and 35-36 are unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

In claim 30, applicant claims the hyaluranic acid has a molecular weight of 200,000 to 2,500,000. As discussed above for claim 1, Hollingsbee et al. teaches use of hyaluronic acid with molecular weights between 200,000 and 2,000,000 and thus claim 30 is unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

In claims 31 and 37, applicant claims that the composition of claim 27 is a solution or a gel (claim 31) or viscous (claim 37) . As discussed above, Hollingsbee et al. teaches that the composition can be used as solution or gel, and it would have been obvious to one of ordinary skill in the art at the time of the invention that a viscous solution or gel would be ideal, as it is a commonly used formulation for wound healing compositions. Thus claims 31 and 37 are unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

Claim 32 claims the composition of claim 27, wherein the hyaluronic acid salt includes sodium salt, which as discussed above for claim 2, is taught by Hollingsbee et al. and thus claim 32 is also unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

In claim 33, applicant claims the composition of claim 27, wherein the hyaluronic acid salt is 0.05-10% by weight of the composition. As discussed above, Hollingsbee et al. teach the hyaluronic acid is 0.1-90% of the composition (page 4, lines 10-12) and thus claim 33 is also unpatentable over Hollingsbee et al. in view of Tsubouchi et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614